DLA PIPER US LLP

1251 Avenue of the Americas New York, NY 10020-1104 (212) 335-4500 Attorneys for Defendants WYETH AND WYETH PHARMACEUTICALS INC.

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

SUSAN MARSA,

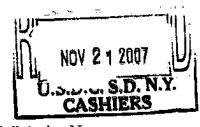
Plaintiff,

- against -

WYETH, WYETH PHARMACEUTICALS INC., WYETH-AYERST PHARMACEUTICALS, INC., WYETH PHARMACEUTICALS, PFIZER INC., PHARMACIA & UPJOHN, INC., PHARMACIA & UPJOHN COMPANY, PHARMACIA & UPJOHN, LLC., PHARMACIA & UPJOHN COMPANY LLC. and PHARMACIA CORPORATION,

Defendants.

07 CV 10542



Civil Action No.

NOTICE OF REMOVAL

PLEASE TAKE NOTICE that Defendants Wyeth and Wyeth Pharmaceuticals Inc., collectively ("Wyeth"), by its undersigned attorneys, hereby removes the state court action to the United States District Court for the Southern District of New York, pursuant to 28 U.S.C. §§ 1441 and 1446. In support of this Notice of Removal, Wyeth states as follows:

Plaintiff also names Wyeth-Ayerst Pharmaceuticals Inc. (incorrectly named as Wyeth-Ayerst Pharmaceuticals, Inc.) and Wyeth Pharmaceuticals. Wyeth-Ayerst Pharmaceuticals Inc. changed its name to Wyeth Pharmaceuticals Inc. on March 22, 2002. Wyeth Pharmaceuticals is a division of Wyeth.

#### THE REMOVED CASE

The removed case is a civil action filed on or about October 16, 2007, in the Supreme Court of the State of New York, County of New York, having been assigned Index No. 07/113891, and titled Susan Marsa v. Wyeth, Wyeth Pharmaceuticals Inc., Wyeth-Ayerst Pharmaceuticals, Inc., Wyeth Pharmaceuticals, Pfizer Inc., Pharmacia & Upjohn, Inc., Pharmacia & Upjohn Company, Pharmacia & Upjohn, LLC., Pharmacia & Upjohn Company LLC. and Pharmacia Corporation.

#### PAPERS FROM REMOVED ACTION

1. As required by 28 U.S.C. § 1446(a), attached as Exhibit A are copies of all process, pleadings, and orders served upon Wyeth in the removed case.

#### THE REMOVAL IS TIMELY

2. Wyeth is informed and believes that the first date upon which Wyeth was served a copy of the Complaint in the removed case was October 26, 2007. This Notice of Removal is filed within 30 days of that service and, therefore, is timely under 28 U.S.C § 1446(b).

#### CONSENT TO REMOVAL

Although the consent of fraudulently joined and unserved defendants is not required, defendants Pfizer Inc., Pharmacia & Upjohn Company LLC (f/k/a "Pharmacia & Upjohn Company") (incorrectly also named herein as "Pharmacia & Upjohn Company,")

Pharmacia & Upjohn LLC (f/k/a "Pharmacia & Upjohn Inc.") (incorrectly also named herein as "Pharmacia & Upjohn Inc.") and Pharmacia Corporation (the "Upjohn Defendants") consent to this Notice of Removal. The written consent to removal is attached at Exhibit B.

#### THE VENUE REQUIREMENT IS MET

4. Venue of this removal is proper under 28 U.S.C. § 1441(a) because this Court is the United States District Court for the district and division corresponding to the place where the state-court action was pending.

# DIVERSITY OF CITIZENSHIP EXISTS BETWEEN THE PROPERLY-JOINED PARTIES

- 5. This is a civil action that falls under the Court's original jurisdiction under 28 U.S.C. § 1332 (diversity of citizenship) and is one that may be removed to this Court based on diversity of citizenship under 28 U.S.C. §§ 1441 and 1446.
- 6. As admitted in the Complaint, the Plaintiff is a resident of New York. See
  Complaint, ¶ 5. Upon information and belief, the Plaintiff is, and was at the time the action was
  commenced, a citizen of New York. The allegations in the Complaint do not contradict Wyeth's
  belief, and the Plaintiff's citizenship has therefore been sufficiently established for purposes of
  supporting federal jurisdiction. See, e.g., Wright v. Continental Cas. Co., 456 F. Supp. 1075,
  1078 (M.D. Fla. 1978) ("[a]llegations in the defendant's petition for removal, if not contradicted
  by the allegations of the complaint, are alone sufficient to establish prima facie the existence of
  federal jurisdiction").
- 7. Defendants Wyeth and Wyeth Pharmaceuticals Inc. are not, and were not at the time the action was commenced, citizens of New York. *See* Complaint, ¶¶ 6-9. Wyeth and Wyeth Pharmaceuticals Inc. are incorporated in Delaware. Wyeth has its principal place of business in New Jersey and Wyeth Pharmaceuticals Inc. has its principal place of business in Pennsylvania.

- Defendant Pharmacia Corporation is not, and was not at the time the action was 8. commenced, a citizen of New York. Pharmacia Corporation is incorporated in Delaware and has its principal place of business in New Jersey.
- Defendant Pharmacia & Upjohn Company LLC is not, and was not at the time the 9. action was commenced, a citizen of New York. Pharmacia & Upjohn Company LLC is, and was at the time of the filing of the complaint, a limited liability company whose sole member is, and was at the time of the filing of the complaint, Pharmacia & Upjohn LLC. Pharmacia & Upjohn LLC is, and was at the time of the filing of the complaint, a limited liability company whose sole member is, and was at the time of the filing of the complaint, Pharmacia Corporation. Thus, Pharmacia & Upjohn Company LLC and Pharmacia & Upjohn LLC have the same citizenship for purposes of federal diversity jurisdiction as Pharmacia Corporation. See ¶ 8, supra.
- Defendant Pfizer Inc. ("Pfizer"), a citizen of New York, has been fraudulently 10. joined in an attempt to destroy diversity and prevent removal. Its citizenship must, therefore, be disregarded for purposes of diversity analysis. See Pampillonia v. RJR Nabisco, Inc., 138 F.3d 459, 460-61 (2d Cir. 1998) (disregarding the citizenship of a fraudulently joined non-diverse defendant in order to assert federal diversity jurisdiction over a case); see ¶¶ 11-18, infra.

# THE NON-DIVERSE DEFENDANT, PFIZER INC., HAS BEEN FRAUDULENTLY JOINED

- Joinder is fraudulent if "there is 'no reasonable basis' for predicting liability on 11. the claims alleged." In re Rezulin Prod. Liab. Litig., 133 F. Supp.2d 272, 280 n.4 (S.D.N.Y. 2001) (citing Pampillonia v. RJR Nabisco, Inc., 138 F.3d 459, 461 n.3 (2d Cir. 1998)).
- Plaintiff has asserted the following claims against Pfizer: strict product liability -12. failure to warn (First Cause of Action, Complaint ¶¶ 119-122); negligence (Second Cause of

Action, Complaint ¶¶ 124-127); breach of implied warranty (Third Cause of Action, Complaint ¶¶ 129-133); breach of express warranty (Fourth Cause of Action, Complaint ¶¶ 135-138); deceit by concealment (Fifth Cause of Action, Complaint ¶ 140-144); negligent misrepresentation (Sixth Cause of Action, Complaint ¶¶ 146-152); and strict product liability – design defect (Seventh Cause of Action, Complaint ¶ 154-163). The allegations in the Complaint are insufficient to establish these claims against Pfizer (or any of the Upjohn defendants).

- 13. Plaintiff does not affirmatively allege she ingested any product manufactured or sold by Pfizer. Plaintiff alleges that she "took Premarin, Provera, and Prempro and/or their generic equivalents." Complaint ¶ 1, 39 (emphasis added). Generic equivalents do not exist for Prempro or Premarin, so Plaintiff specifically alleges ingestion of both Prempro and Premarin. However, generic equivalents manufactured and sold by entities who are not parties to this action exist for Provera (medroxyprogesterone acetate "MPA") (a product which Plaintiff alleges was manufactured and sold by Upjohn Defendants) and, thus, Plaintiff may not have ingested Pfizer's or any Upjohn Defendant's drug. This ambiguous statement is not the same as an affirmative allegation that she took a Pfizer (or any Upjohn Defendant's) product and it reflects that Plaintiff does not have a reasonable, good-faith basis for her allegations against Pfizer. See In re Rezulin Prods. Liability Litig., 133 F.Supp. 2d 272, 280 (articulating that the standard for fraudulent joinder is whether a plaintiff has a reasonable possibility to assert a cause of action against defendant).
- 14. Under New York law, there can be no liability without a duty running to the injured person. Lauer v. City of New York, 95 N.Y.2d 95, 100 (2000). In the absence of any specific allegation that Plaintiff used a product manufactured by Pfizer, Pfizer owes no duty to Plaintiff and, consequently, there is no reasonable basis for any of the Complaint's causes of

was too remote).

action against Pfizer. See In re Consolidated FenPhen Cases, 2003 WL 22682440 \*6-7 (E.D.N.Y. Nov. 12, 2003) (finding that Wyeth-Ayerst International Inc. owed no duty to plaintiff because, when it did not manufacture the product that plaintiff used, its connection to plaintiff

- 15. Even if the Complaint can be read to allege that Pfizer is liable under a concerted action theory (which it cannot), the allegations in the Complaint are insufficient to establish such a cause of action against Pfizer.
- The elements of concerted action are "(1) an understanding 'express or tacit, to 16. participate in a common plan or design to commit a tortious act,' (2) that each defendant acted tortiously and (3) that one of the defendants committed an act which constitutes a tort in pursuance of the agreement." Cresser v. American Tobacco Co., 174 Misc.2d 1, n.4, 662 N.Y.S.2d 374 (N.Y. Sup. 1997) (citing Halberstam v. Welch, 705 F.2d 472, 477 (D.C. Cir. 1983)). Here, the Complaint fails to allege these elements. First, there is no allegation that Wyeth and Pfizer entered into an unlawful agreement beyond conclusory allegations that each of the defendants was the "agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other defendants" and that each defendant "rendered substantial assistance and encouragement" to the other defendants' alleged breach of duties. See Complaint ¶ 2. Second, there is no allegation that Pfizer acted tortiously with respect to the Plaintiff. The allegation that Pfizer failed to disclose the risks of the MPA it manufactured does not constitute a tort when there is no allegation that the Plaintiff used Pfizer's MPA. Further, there is no allegation that Pfizer knew of the alleged risks of Wyeth's products, Prempro or Premarin, and no duty for Pfizer to disclose such risks even if it knew about them. Third, there is no allegation that Wyeth acted tortiously pursuant to an agreement with Pfizer.

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- Because the Complaint fails to allege any viable causes of action against Pfizer, 17, Pfizer is fraudulently joined, and its citizenship must be disregarded for diversity purposes. See Pampillonia v. RJR Nabisco, Inc., 138 F.3d 459, 460-61 (2d Cir. 1998) (disregarding the citizenship of a fraudulently joined non-diverse defendant in order to assert federal diversity jurisdiction over a case).
- Because the Plaintiff is a citizen of New York, and the properly-joined defendants 18. are not, complete diversity of citizenship exists under 28 U.S.C. § 1332.

# THE AMOUNT-IN-CONTROVERSY REQUIREMENT IS SATISFIED

- The monetary value of the amount in controversy exceeds \$75,000, exclusive of 19. interests and costs.
- Whether a case properly can be removed "is determined by the allegations of the 20. complaint if it sets up the amount in controversy, and, if it does not, the court may look to the petition for removal." Davenport v. Procter & Gamble Mfg. Co., 241 F.2d 511, 514 (2d Cir. 1957); Mehlenbacher v. Akzo Nobel Salt, Inc., 216 F.3d 291, 296 (2d Cir. 2000); Dri Mark Products, Inc. v. Meyercord Co., 194 F. Supp. 536, 537 (S.D.N.Y. 1961).
- 21. Plaintiff seeks compensatory damages arising out of the use of the prescription hormone replacement products. The face of the Complaint makes clear that the Plaintiff seeks damages in excess of \$75,000, for Plaintiff alleges the following injuries/damages:

"Plaintiff asserts a claim for personal injury, breast cancer, caused by her ingestion of combination hormone replacement products." See Complaint, ¶ 1 (emphasis added).

22. Reported verdicts and settlements in cases where the alleged injury is breast cancer indicate that damages in such cases exceed \$75,000. See Rozar v. Kaiser Foundation Healthcare, 21 No. 8 Verdict Settlements & Tactics ("VST") 348 (Westlaw 2000) (\$842,680 arbitration award for delay in diagnosing breast cancer); Howstow v. Rosenburg, 21 No.2 VST 65 (Westlaw 2000) (\$750,000 verdict in suit alleging failure to diagnose breast cancer); Mathews v. Bloy, 19 No.4 VST 141 (Westlaw 1999) (\$400,000 awarded in suit alleging failure to diagnose breast cancer); Ruffin v. Medical Ctr. Radiology Group, 15 No.7 VST 238 (Westlaw 1995) (\$2.6 million awarded to plaintiff in suit alleging failure to diagnose breast cancer); Greeley v. Slepian, 12 No. 8 VST 280 (Westlaw 1992) (\$1.4 million arbitration award for failure to diagnose breast cancer).

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- 23. Plaintiff also seeks punitive damages. See Complaint, ¶ 163. Punitive damages are included in the calculation of the amount in controversy. See Bell v. Preferred Life

  Assurance Society, 320 U.S. 238, 240 (1943) ("[w]here both actual and punitive damages are recoverable under a complaint each must be considered to the extent claimed in determining jurisdictional amount"). The totality of these factors establishes that the amount in controversy meets the jurisdictional requirement.
- 24. Thus, the state court action may be removed to this Court by Wyeth in accordance with the provisions of 28 U.S.C. § 1441(a) because (i) this action is a civil action pending within the jurisdiction of the United States District Court for the Southern District of New York; (ii) this action is between citizens of different states; and (iii) the amount in controversy exceeds \$75,000, exclusive of interest and costs.

#### MULTIDISTRICT LITIGATION

25. On March 4, 2003, the Judicial Panel on Multidistrict Litigation granted a motion to consolidate pursuant to 28 U.S.C. § 1407, created *In re Prempro Products Liability Litigation*, MDL-1507, and transferred all Prempro litigation to the Eastern District of Arkansas (Judge William R. Wilson). Wyeth will identify this removed case as a "tag-along" action, and it can be expected that the Panel will shortly issue a Conditional Transfer Order transferring this case to the Eastern District of Arkansas.

#### FILING OF REMOVAL PAPERS

26. Pursuant to 28 U.S.C. § 1446(d), written notice of the removal of this action has been given simultaneously to Plaintiffs' counsel, and a Notice of Filing of Notice of Removal is simultaneously being filed with the Supreme Court of the State of New York, County of New York. A true and correct copy of this Notice is attached hereto as Exhibit C.

WHEREFORE, Wyeth hereby removes the above-captioned action from the Supreme Court of the State of New York, County of New York, and requests that further proceedings be conducted in this Court as provided by law.

Dated:

New York, New York November 21, 2007

Heidi Levine, Esq.

Eric M. Falkenberry, Esq. 1251 Avenue of the Americas New York, New York 10020-1104

212-335-4500

Attorneys for Defendants

Wyeth and Wyeth Pharmaceuticals Inc.

#### ON NOTICE TO:

Andrew G. Finkelstein, Esq. Finkelstein & Partners, LLP 436 Robinson Avenue Newburgh, New York 12550

Attorneys for Plaintiff

Alan E. Rothman, Esq. Kaye Scholer LLP 425 Park Avenue New York, New York 10022-3598

Attorneys for Defendants Pfizer Inc.,
Pharmacia & Upjohn Company LLC (f/k/a
"Pharmacia & Upjohn Company")
(incorrectly also named herein as
"Pharmacia & Upjohn Company,")
Pharmacia & Upjohn LLC (f/k/a "Pharmacia & Upjohn Inc.") (incorrectly also named herein as "Pharmacia & Upjohn Inc.") and
Pharmacia Corporation

# EXHIBIT A

Filed 11/21/20/07 OF PRINC 16/01/6/07

INDEX #:

Plaintiff designates New York County as the place of trial.

The basis of venue is: Plaintiff(s) residence.

Plaintiff resides at: 20 Park Avenue New York, New York County of New York.

SUPREME COURT STATE OF NEW YORK COUNTY OF NEW YORK

SUSAN MARSA.

Plaintiff(s).

SUMMONS

-against-

WYETH, WYETH PHARMACEUTICALS INC., WYETH-AYERST PHARMACEUTICALS, INC., WYETH PHARMACEUTICALS, PFIZER INC., PHARMACIA & UPJOHN, INC., PHARMACIA & UPJOHN COMPANY, PHARMACIA & UPJOHN, LLC., PHARMACIA & UPJOHN COMPANY LLC. and PHARMACIA CORPORATION.

Defendant(s).

To the above named defendant(s):

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiff's Attorney(s) within -20- days after the service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

> FINKELSTEIN & PARTNERS, LLP Attorneys for Plaintiff(s) 436 Robinson Avenue Newburgh, New York 12550

> > 1-845-562-0203

ANDREW G. FINKELSTEIN, ESQ.

Dated: October 4 DEFENDANT'S ADDRESS: EE VERIFIED COMPLAINT

GCT 26 2011

WILLIAM J. RUANE

File #246949-06/hc

STATE OF NEW YORK
SUPREME COURT: COUNTY OF NEW YORK
SUSAN MARSA,

Plaintiff,

-against-

VERIFIED COMPLAINT

WYEIH, WYETH PHARMACEUTICALS INC.,
WYEIH-AYERST PHARMACEUTICALS, INC.,
WYETH PHARMACEUTICALS, PFIZER INC.,
PHARMACIA & UPJOHN, INC.,
PHARMACIA & UPJOHN COMPANY,
PHARMACIA & UPJOHN LLC.,
PHARMACIA & UPJOHN COMPANY LLC. and
PHARMACIA CORPORATION,

Defendants.

Plaintiff, by attorneys, FINKELSTEIN & PARTNERS, LLP, as and for the Verified Complaint herein allege upon information and belief the following:

#### STATEMENT OF THE CASE

1. This is an action for personal injuries and damages brought on behalf of plaintiff SUSAN MARSA, who has been prescribed and was supplied with, received, and who has taken and ingested and consumed the prescribed drugs Premarin (conjugated estrogen), Provera (medroxyprogesterone acetate) and Prempro, brand names and/or their generic equivalents, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, or otherwise placed in the stream of commerce and sold by Defendants. Plaintiff asserts a claim for personal injury, breast cancer,

caused by her ingestion of combination hormone replacement products, brand name and/or their generic equivalents, consisting of estrogens and progestins or combinations containing estrogen and progestins. This action seeks, among other relief, general and special damages in addition to medical monitoring and equitable relief in order to enable plaintiff to treat and/or monitor the dangerous, severe, and life-threatening conditions caused by these drugs.

- 2. At all times herein mentioned, each of the defendants was the agent, servant, partner, aider and abettor, coconspirator and/or joint venturer of each of the other defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other defendants, knowing that their conduct constituted a breach of duty owed to plaintiff.
- There exists and, at all times herein mentioned, there existed, a unity of interest in ownership between certain defendants and other certain defendants such that any individuality and separateness between the certain defendants has ceased and these defendants are the alter ego of the other certain defendants and exerted control over those defendants. Adherence to the fiction of the separate existence of these certain defendants as an entity distinct from other certain defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice. .
- The injuries of plaintiff were caused by the wrongful acts, omissions, and fraudulent misrepresentations of defendants, all of which occurred within the State of New York.

# PARTIES AND JURISDICTION

5. At all times herein mentioned, plaintiff was and still is a resident of the County of New York, State of New York,

- At all times hereinafter mentioned, upon information and belief, defendant WYETH, was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH has its principal place of business at 5 Giralda Farms, Madison, New Jersey. WYETH is licensed to do business in all states of the United States of America including the State of New York. WYETH regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, pharmaceutical products, including, but not limited to Prempro and Premarin. Plaintiff alleges that WYETH does business in the State of New York and at all times relevant hereto it developed, manufactured, and sold in interstate commerce the faforementioned drugs in the State of New York.
- 7. On March 11, 2002, defendant WYETH-AYERST PHARMACEUTICALS, INC., changed its name to WYETH PHARMACEUTICALS INC. WYETH PHARMACEUTICALS INC. WYETH PHARMACEUTICALS INC., a division of WYETH, was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH PHARMACEUTICALS INC. has its principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426. WYETH PHARMACEUTICALS INC. is licensed to do business in all states of the United States of America including the State of New York. WYETH PHARMACEUTICALS INC. regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH PHARMACEUTICALS INC. was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through

third parties or related entities, pharmaceutical products, including but not limited to, Prempro and Premarin. Plaintiff alleges that WYETH PHARMACEUTICALS INC. does business in the State of New York and at all times relevant hereto it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in the State of New York. Further, WYETH PHARMACEUTICALS INC. either is now or was during the relevant time frame, a subsidiary of defendant WYETH, and such defendant is responsible for all liabilities and obligations to this defendant.

8. At all times hereinafter mentioned, upon information and belief, defendant WYETH-AYERST PHARMACEUTICALS, INC., a division of WYETH, was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH-AYERST PHARMACEUTICALS, INC, has its principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426. WYETH-AYERST PHARMACEUTICALS, INC., is licensed to do business in all states of the United States of America, including the State of New York. WYETH-AYERST PHARMACEUTICALS, INC., regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH-AYERST PHARMACEUTICALS, INC., was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities pharmaceutical products, including, but not limited to, Prempro and Premarin. Plaintiff alleges that WYETH-AYERST PHARMACEUTICALS, INC., does business in the State of New York and at all times relevant hereto it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in the State of New York. Further, WYETH-AYERST PHARMACEUTICALS, INC., either is now or was during the relevant time frame, a

subsidiary of defendant WYETH, and such defendant is responsible for all liabilities and obligations to this defendant.

- At all times hereinafter mentioned, upon information and belief, defendant WYETH PHARMACEUTICALS, a division of WYETH, was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH PHARMACEUTICALS has its principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426. WYETH PHARMACEUTICALS is licensed to do business in all states of the United States of America including the State of New York. WYETH PHARMACEUTICALS regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH PHARMACEUTICALS was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, pharmaceutical products, including but not limited to, Prempro and Premarin. Plaintiff alleges that WYETH PHARMACEUTICALS does business in the State of New York and at all times relevant hereto it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in the State of New York. Purther, WYETH PHARMACEUTICALS either is now or was during the relevant time frame, a subsidiary of defendant WYETH, and such defendant is responsible for all liabilities and obligations to this defendant.
- 10. At all times herein mentioned, upon information and belief, defendant PFIZER INC. was and still is a domestic corporation organized and existing under and by virtue of the Laws of the State of New York.
- 11. At all times herein mentioned, upon information and belief, defendant PFIZER INC. was and still is a foreign corporation duly incorporated within the State of Delaware.

- At all times herein mentioned, upon information and belief, defendant PFIZER 12. INC., was and still is a foreign corporation authorized t do business in the State of New York.
- 13. At all times herein mentioned, upon information and belief, defendant PFIZER INC. was and still is a business entity doing business within the State of New York.
- **I4**. At all times herein mentioned, upon information and belief, defendant PHARMACIA & UPJOHN, INC., was and still is a domestic corporation organized and existing under and by virtue of the Laws of the State of New York.
- At all times herein mentioned, upon information and belief, defendant PHARMACIA & UPIOHN, INC., was and still is a foreign corporation duly incorporated within the State of Delaware.
- At all times herein mentioned, upon information and belief, defendant 16. PHARMACIA & UPIOHN, INC., was and still is a foreign corporation authorized to do business in the State of New York.
- At all times herein mentioned, upon information and belief, defendant PHARMACIA & UPIOHN, INC., was and still is a business entity doing business within the State of New York.
- 18. At all times herein mentioned, upon information and belief, defendant PHARMACIA & UPIOHN COMPANY was and still is a domestic corporation organized and existing under and by virtue of the Laws of the State of New York.
- 19. At all times herein mentioned, upon information and belief, defendant PHARMACIA & UPIOHN COMPANY was and still is a foreign corporation duly incorporated within the State of Delaware.

- 20. At all times herein mentioned, upon information and belief, defendant,

  PHARMACIA & UPJOHN COMPANY was and still is a foreign corporation authorized t do

  business in the State of New York.
- 21. At all times herein mentioned, upon information and belief, defendant

  PHARMACIA & UPJOHN COMPANY was and still is a business entity doing business within
  the State of New York.
- 22. At all times herein mentioned, upon information and belief, defendant

  PHARMACIA & UPJOHN LLC was and still is a domestic corporation organized and existing
  under and by virtue of the Laws of the State of New York.
- 23. At all times herein mentioned, upon information and belief, defendant

  PHARMACIA & UPJOHN LLC.was and still is a foreign corporation duly incorporated within
  the State of Delaware.
- 24. At all times herein mentioned, upon information and belief, defendant PHARMACIA & UPJOHN LLC. was and still is a foreign corporation authorized to do business in the State of New York.
- 25. At all times herein mentioned, upon information and belief, defendant

  PHARMACIA & UPJOHN LLC. was and still is albusiness entity doing business within the

  State of New York.
- 26. At all times herein mentioned, upon information and belief, defendant

  PHARMACIA & UPJOHN COMPANY LLC. was and still is a domestic corporation organized

  and existing under and by virtue of the Laws of the State of New York.

- 27. At all times herein mentioned, upon information and belief, defendant PHARMACIA & UPJOHN COMPANY LLC. was and still is a foreign corporation duly incorporated within the State of Delaware.
- 28. At all times herein mentioned, upon information and belief, defendant

  PHARMACIA & UPJOHN COMPANY LLC. was and still is a foreign corporation authorized to do business in the State of New York.
- 29. At all times herein mentioned, upon information and belief, defendant PHARMACIA & UPJOHN COMPANY LLC. was and still is a business entity doing business within the State of New York.
- 30. At all times herein mentioned, upon information and belief, defendant PHARMACIA CORPORATION was and still is a domestic corporation organized and existing under and by virtue of the Laws of the State of New York.
- 31. At all times herein mentioned, upon information and belief, defendant

  PHARMACIA CORPORATION was and still is a foreign corporation duly incorporated within
  the State of Delaware.
- 32. At all times herein mentioned, upon information and belief, defendant PHARMACIA CORPORATION was and still is a foreign corporation authorized to do business in the State of New York.
- 33. At all times herein mentioned, upon information and belief, defendant PHARMACIA CORPORATION was and still is a business entity doing business within the State of New York.
- 34. At all times mentioned, defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching.

designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling the prescribed medication products known as "hormone therapy" for the use and ingestion by plaintiff.

- At all times herein mentioned, defendants, and each of them, were authorized to do business within the State of New York and did in fact supply, distribute, and sell the aforementioned drugs within the State of New York.
- 36. At all times herein mentioned, the officers and/or directors of defendants participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products and thereby actively participated in the tortious conduct which resulted in the injuries suffered by plaintiff.
- 37. At all times herein mentioned, defendants, and each of them, were engaged in the business of prescribing, formulating, distributing, supplying and selling hormone therapy products.
- 38. Plaintiff files this lawsuit within three years of first suspecting that said drugs were the cause of any appreciable harm sustained by plaintiff. Plaintiff could not by the exercise or reasonable diligence have discovered the wrongful cause of plaintiff's injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when plaintiff's injuries were discovered their cause was unknown to plaintiff. Plaintiff did not suspect, nor did plaintiff have reason to suspect, that plaintiff had been injured, the cause of the injury, or the tortious nature of the conduct causing injury, until less than three year prior to the filing of this action. Additionally, plaintiff was prevented from discovering this information sooner because

defendants misrepresented and continue to misrepresent to the public and to the medical profession that the drugs are safe and free from serious side effects, and defendants have fraudulently concealed facts and information that could have led plaintiff to discover a potential cause of action. Therefore, the statute of limitations is equitably tolled as to these defendants.

#### PARTIES

### The Plaintiff:

39. Plaintiff SUSAN MARSA, who resides in the County of New York, State of New York, took Premarin, Provera and Prempro and/or their generic equivalents, and was injured as a result of her ingestion of the hormone therapy products.

# The Defendants:

- 40. Defendants manufactured, marketed, sold and distributed hormone therapy products.
- 41. Defendants are in the business of selling, assembling, inspecting, marketing, promoting, packaging and/or advertising hormone therapy products for sale to plaintiff. Defendants owed a duty to plaintiff to provide warnings about the proper use and side effects of hormone therapy products to plaintiff.
- 42. At all times hereinafter mentioned, upon information and belief, defendant WYETH was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH has its principal place of business at 5 Giralda Farms, Madison, New Jersey. WYETH is licensed to do business in all states of the United States of America including the State of New York. WYETH regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH was engaged in the

business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, pharmaceutical products, including, but not limited to Prempro and Premarin. Plaintiff alleges that WYETH does business in the State of New York and at all times relevant hereto it developed, manufactured, and sold in interstate commerce the aforementioned drugs in the State of New York.

43. At all times hereinafter mentioned, upon information and belief, defendant WYEIH-AYERST PHARMACEUTICALS, INC., a division of WYEIH, was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH-AYERST PHARMACEUTICALS, INC, has its principal place of business at 500 Arcola Road. Collegeville, Pennsylvania 19426. WYETH-AYERST PHARMACEUTICALS, INC, is licensed to do business in all states of the United States of America, including the State of New York. WYETH-AYERST PHARMACEUTICALS, INC., regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH-AYERST PHARMACEUTICALS, INC., was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities pharmaceutical products, including, but not limited to, Prempro and Premarin. Plaintiff alleges that WYETH-AYERST PHARMACEUTICALS, INC., does business in the State of New York and at all times relevant hereto it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in the State of New York. Further, WYETH-AYERST PHARMACEUTICALS, INC., either is now or was during the relevant time frame, a subsidiary of defendant WYETH, and such defendant is responsible for all liabilities and obligations to this defendant.

- On March 11, 2002, defendant WYETH-AYERST PHARMACEUTICALS, INC., changed its name to WYETH PHARMACEUTICALS INC. WYETH PHARMACEUTICALS INC., a division of WYETH, was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH PHARMACEUTICALS INC. has its principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426. WYETH PHARMACEUTICALS INC. is licensed to do business in all states of the United States of America including the State of New York. WYETH PHARMACEUTICALS INC. regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH PHARMACEUTICALS INC. was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, pharmaceutical products, including but not limited to, Prempro and Premarin. Plaintiff alleges that WYETH PHARMACEUTICALS INC. does business in the State of New York and at all times relevant hereto it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in the State of New York. Further, WYETH PHARMACEUTICALS INC. either is now or was during the relevant time frame, a subsidiary of defendant WYETH, and such defendant is responsible for all liabilities and obligations to this defendant.
- 45. At all times hereinafter mentioned, upon information and belief, defendant WYETH PHARMACEUTICALS, a division of WYETH, was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH PHARMACEUTICALS has its principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426. WYETH PHARMACEUTICALS is licensed to do business in all states of the United States of America

including the State of New York. WYETH PHARMACEUTICALS regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH PHARMACEUTICALS was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, pharmaceutical products, including but not limited to, Prempro and Premarin. Plaintiff alleges that WYETH PHARMACEUTICALS does business in the State of New York and at all times relevant hereto it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in the State of New York. Further, WYETH PHARMACEUTICALS either is now or was during the relevant time frame, a subsidiary of defendant WYETH, and such defendant is responsible for all liabilities and obligations to this defendant.

46. Defendant PFIZER INC, is a foreign corporation organized and existing under the laws of the State of New York and is headquartered in New York City, New York. PFIZER INC. regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. PFIZER INC. purchased the business of and merged with PHARMACIA AND UPJOHN and has thereby assumed any and all liability on the part of PHARMACIA AND UPIOHN with respect to the licensing, manufacturing, distributing and/or selling of Provera and medroxyprogesterone acetate (MPA). Plaintiff alleges on information and belief that PFIZER. INC. does business in New York and this County and at all times relevant hereto, through PHARMACIA AND UPIOHN, it developed, manufactured, and sold in interstate commerce and in New York and this County, the aforementioned drug.

- Defendant, PHARMACIA & UPJOHN, INC., was a citizen of and incorporated 47. in the State of Delaware. PHARMACIA & UPJOHN, INC., had its principal place of business in the State of New Jersey. PHARMACIA & UPJOHN, INC., was licensed to do business in all states of the United States of America including the State of New York, PHARMACIA & UPJOHN, INC., regularly conducted, and continued to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, PHARMACIA & UPJOHN, INC., was engaged in the business of licensing, manufacturing, distributing and/or selling, either directly or indirectly, through third parties or related entities, the pharmaceutical products Provers and medroxyprogesterone acetate (MPA), brand names and/or generic equivalents. Plaintiff alleges on information and belief that PHARMACIA & UPJOHN, INC., did business in New York and at all times relevant hereto, it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in New York.
- 48. Defendant PHARMACIA & UPJOHN COMPANY was a citizen of and incorporated in the State of Delaware. PHARMACIA & UPJOHN COMPANY had a principal place of business in the State of Michigan. PHARMACIA & UPJOHN COMPANY was licensed to do business in all states of the United States of America including the State of New York. PHARMACIA & UPJOHN COMPANY regularly conducted, and continued to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, PHARMACIA & UPJOHN COMPANY was engaged in the business of licensing. manufacturing, distributing and/or selling, either directly or indirectly, through third parties or related entities, the pharmaceutical products Provera and medroxyprogesterone acetate (MPA),

brand names and/or generic equivalents. Plaintiff alleges on information and belief that PHARMACIA & UPJOHN COMPANY did business in New York and at all times relevant hereto, it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in New York.

- 49. On or about August 13, 2004, defendant PHARMACIA & UPJOHN, INC., converted to a Delaware limited liability company named PHARMACIA & UPJOHN LLC.
- 50. On or about August 13, 2004, defendant, PHARMACIA & UPJOHN COMPANY converted to a Delaware limited liability company named PHARMACIA & COMPANY LLC.
- Upjohn Company, fka The Upjohn Company of Delaware, fka The Upjohn Company), is a Delaware limited liability company whose sole member is PHARMACIA & UPJOHN LLC. PHARMACIA & UPJOHN COMPANY LLC is a successor in interest to PHARMACIA & UPJOHN COMPANY, and assumed all debts, liabilities and duties of PHARMACIA & UPJOHN COMPANY. PHARMACIA & UPJOHN COMPANY LLC is licensed to do business in all states of the United States of America including the State of New York. PHARMACIA & UPJOHN COMPANY LLC regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, PHARMACIA & UPJOHN COMPANY LLC was engaged in the business of licensing, manufacturing, distributing and/or selling, either directly or indirectly, through third parties or related entities, the pharmaceutical products Provera and medroxyprogesterone acetate (MPA), brand names and/or generic equivalents. Plaintiff alleges on information and belief that PHARMACIA & UPJOHN

COMPANY LLC does business in New York and at all times relevant hereto, it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in New York.

- 52. Defendant PHARMACIA & UPJOHN LLC, (fka Pharmacia & Upjohn, Inc.), is a Delaware limited liability company whose sole member is PHARMACIA CORPORATION. PHARMACIA & UPJOHN LLC is a successor in interest to PHARMACIA & UPJOHN, INC., and assumed all debts, liabilities and duties of PHARMACIA & UPJOHN, INC. PHARMACIA & UPJOHN LLC is licensed to do business in all states of the United States of America including the State of New York. PHARMACIA & UPIOHN LLC regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, PHARMACIA & UPIOHN LLC was engaged in the business of licensing, manufacturing, distributing and/or selling, either directly or indirectly, through third parties or related entities, the pharmaceutical products Provera and medioxyprogesterone acetate (MPA), brand names and/or generic equivalents. Plaintiff alleges on information and belief that PHARMACIA & UPJOHN LLC does business in New York and at all times relevant hereto, it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in New York.
- 53. Defendant PHARMACIA CORPORATION is a citizen of and incorporated in the State of Delaware. PHARMACIA CORPORATION has its principal place of business in the State of New Jersey. PHARMACIA CORPORATION is licensed to do business in all states of the United States of America including the State of New York. PHARMACIA CORPORATION regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this

Court. At all times relevant hereto, PHARMACIA CORPORATION is engaged in the business of licensing, manufacturing, distributing and/or selling, either directly or indirectly, through third parties or related entities, the pharmaceutical products Provera and medroxyprogesterone acetate (MPA), brand names and/or generic equivalents. Plaintiff alleges on information and belief that PHARMACIA CORPORATION does business in New York and at all times relevant hereto, it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in New York. Further, PHARMACIA CORPORATION either is now or was during the relevant time frame, a subsidiary of Defendant, PFIZER INC., and such Defendant is responsible for all liabilities and obligations to this Defendant.

54. Defendant PFIZER INC., (fka Chas. Pfizer & Co.), is a citizen of and incorporated in the State of Delaware with its principal place of business in the State of New York. PFIZER INC. is licensed to do business in all states of the United States of America, including the State of New York. PFIZER INC. regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, PFIZER INC. was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, pharmaceutical products, including but not limited to, Provera and medroxyprogesterone acetate (MPA), brand names and/or generic equivalents. Plaintiff alleges that PFIZER INC. does business in New York and at all times relevant hereto developed, manufactured, and sold that aforementioned drugs in interstate commerce and in New York. On information and belief, a merger between Defendant, PFIZER INC. and PHARMACIA CORPORATION, including its subsidiary, PHARMACIA & UPJOHN COMPANY, has made defendant PFIZER INC. responsible for the

obligations, debts and liabilities of PHARMACIA & UPIOHN, INC., PHARMACIA & UPJOHN COMPANY LLC, PHARMACIA & UPJOHN LLC'and PHARMACIA CORPORATION, with respect to the licensing, manufacturing, distributing and/or selling of these hormone medications. Plaintiff alleges on information and belief that PFIZER INC, does business in New York and at all times relevant hereto, through PHARMACIA & UPJOHN COMPANY LLC, it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in New York.

55. The above list is intended to include each company's subsidiaries, divisions, franchises, partners, joint venturers, organizational units of any kind, their predecessors, their successors and assigns, and their present officers, directors, employees, agents, representatives and other persons acting on their behalf. Plaintiff will seek leave of the court to amend the complaint to include any or all of these companies, once plaintiff has discovered which company/companies manufactured and/or distributed said drugs she ingested.

# GENERAL ALLEGATIONS/FACTUAL BACKGROUND

- 58. Plaintiff brings this action to recover damages for personal injuries against defendants, which tested, manufactured, marketed, labeled, distributed, promoted, prescribed and sold Premarin, Provera and Prempro.
- 59. A variety of prescribed oral hormone therapy drugs exist and have existed for peri-menopausal women which contain both estrogen and progestins. These drugs can be ingested in combination form (one pill) or separately (i.e. conjugated estrogen and a form of progestin). One of these drugs, Prempro, which is also known by its pharmaceutical name, conjugated equine estrogens/medroxyprogesterone acetate (progestin) is considered a combination hormone therapy because it contains a combination of two hormones, estrogen and

progestin.

- 60. Estrogen therapy refers to use of estrogen alone for hormone therapy. Among the most prescribed brands of estrogen is the Wyeth Defendants' product, Premarin, which is also known by its pharmaceutical name, conjugated equine estrogens.
- 61. In addition to manufacturing the hormone therapy drugs, Prempro and Premarin, the Wyeth Defendants along with the MPA Defendants manufactured and distributed another hormone drug, medroxyprogesterone acetate, which is a synthetic progestin that when taken concurrently with Premarin constitutes a form of combination hormone therapy that is pharmaceutically equivalent to the Prempro tablet.
- 62. Hormone therapy medication has been marketed to women who are going through menopause. Menopause describes a time in the natural aging process of a woman when her body's production of the natural hormones estrogen and progesterone is dramatically reduced. There are physical changes to a woman when her levels of estrogen and progesterone drop so dramatically. These consequences include symptoms such as mood swings, hot flashes, loss of bone density, depression, irritability, night sweats and forgetfulness. These symptoms range from severe and disabling in some women to a minor inconvenience form other women.
- 63. In 1942, Ayerst, the predecessor to Wyeth and Wyeth Pharmaceuticals, (and hereinafter Wyeth) received approval for Premarin, which is a conjugated equine estrogen made from the urine of pregnant mares. Premarin has remained chemically unchanged until today.

  Wyeth began marketing its product as a hormone replacement product, to replace the natural female hormone estrogen.
- 64. Defendants have vigorously promoted their menopausal hormone therapy products using a variety of marketing messages that emphasize the use of these medications

long-term. Indeed, one of the 1973 key marketing statement for Premarin was "start her on, keep her on". Even as late as 1991, Wyeth still represented that "protection continued only as long as estrogen therapy continued."

- To get this message out to the patients and the doctors, Defendants have used the following marketing methods to promote their products:
  - Sponsoring medical journal articles about the benefits of its products; A.
- B. Detailing /sales representatives calling on and encouraging physicians to prescribe the drugs;
- Sponsored continuing medical education programs discussing the benefits of its C. products;
- Hiring experts in the field to speak to other physicians either one on one or in small group meetings;
  - Press releases; E,
  - Direct to consumers advertisements about the products; P.
  - Advertisements directed to physicians in medical journals and materials; G.
- Sponsoring medical and pseudo-medical organizations to make statements H. supporting the use of the products.
- Defendants have also extensively represented through the methods listed above, 66. the negative health effects of menopause ranging from symptoms like hot flashes, night sweats and mood changes to an increased risk of life changing and life threatening conditions like cardiovascular problems, osteoporosis and dementia. Through their marketing and advertising efforts, Defendants have convinced doctors and patients that menopause was not the natural process of aging, but instead immed this process into a disease in need of drug treatment.

- Several decades ago, defendant Wyeth attempted to disguise menopause as a 67. disease. In 1962, Dr. Robert Wilson, a New York, gynecologist, published an article in the Journal of the American Medical Association (JAMA), that claimed estrogen taken during menopause could reduce breast and genital cancers. A few years later, in 1966, Dr. Wilson published a bestseller book entitled Feminine Forever. In Feminine Forever, Dr. Wilson recommended estrogen as the "cure" for "the tragedy of menopause." He argued that women who use the drugs "will be much more pleasant to live with and will not become dull and unattractive." In writing about the menopause condition, which he termed the "deficiency disease," Dr. Wilson wrote that "aside from keeping a woman sexually attractive and potent . . . estrogen preserves the strength of her bones, the glow of her skin, the gloss of her hair . . . Estrogen makes women adaptable, even-tempered, and generally easy to live with." Dr. Wilson asserted that estrogen prevents breast and genital cancers, such as endometrial cancer (i.e., cancer of the uterine lining). Unbeknownst to readers, Dr. Wilson was financially supported by Wyeth to write, publish, promote and market this book. While disguised as an independent project, Feminine Forever, was nothing more than a best selling promotional piece for Wyeth's estrogen products. There was no reliable science to support Dr. Wilson's assertions or claimed benefits.
- Soon after the publication of Dr. Wilson's book, Wyeth's sales force began to distribute the book to physicians throughout the country. Wyeth spent thousands of dollars supporting Dr. Wilson's promotional book tour and sales of Premarin increased dramatically.
- 69. In 1974 and 1975, Wyeth started a round of advertising that recommended Premarin as an alternative treatment to tranquillizers for the treatment of symptomatic or mild depression caused by menopause. In a print advertisement that Wyeth published in the October

- 13, 1975, edition of *JAMA*, Wyeth claimed that "tension, irritability, headaches, undue fatigue, depression and insomnia," when caused by declining menopausal estrogen levels, may be relieved with Premarin. Additionally, at the top of the advertisement, in large print, Wyeth advised doctors, "Almost any tranquilizer might calm her down . . . but at her age, estrogen may be what she really needs." The 1975 advertisements stated: "in the treatment of middle-aged depression, there may be one thing to add... Premarin." Again no clinical studies or reliable science supported these representations.
- 70. In 1977, the Food & Drug Administration (FDA) issued a statement confirming that estrogen therapy should not be used to treat simple nervousness during menopause and that there was no scientific support for any representation that such therapy could keep a woman feeling young or her skin soft.
- 71. By the mid-70s more than 30 million prescriptions for Premarin were being written every year, eventually making it the fifth most frequently prescribed drug in the United States.
- 72. Then the first hormone therapy health epidemic arose. In the New England Iournal of Medicine (NEIM) in 1975, two articles appeared that linked estrogen therapy to a significantly increased risk of women developing endometrial cancer. Quickly physicians stopped prescribing Premarin for women with intact uteri. Estrogen sales plummeted and by 1979, the only approved use of estrogen was for treatment of hot flashes and vaginal dryness.
- 73. In 1979, Dr. Robert Greenblatt published an article in the Journal of Geriatrics Society which reported that "estrogen related uterine cancer can be avoided if progesterone is added to the regimen". Wyeth and the other drug manufacturers immediately started promoting combination hormone therapy.

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- In order to obtain a patent on the product, Pfizer developed a synthetic hormone 74. product called medroxyprogesterone acetate or MPA that was marketed under the brand name Provera. Later other defendants began manufacturing this drug. This drug does not have the same chemical or pharmacological effect as the natural hormone progesterone. From the early 1980s until 1995, a common combination prescription was the use of Premarin with Provera. Indeed, in 1985, the Pfizer advertising campaign for Provera was a color advertisement featuring Premarin and Provera as the preferred hormone therapy combination.
- Other Defendant drug companies have also created alternate estrogen products as well as MPA products for use in hormone therapy.
- In 1985, Wyeth added a new spin to the marketing of hormone therapy drugs by claiming that the drugs could help prevent bone loss. Wyeth hired a public relations firm to create public awareness of osteoporosis and learned that 77% of women had never heard of osteoporosis. As a result, Wyeth's public relations campaign informed women that osteoporosis is a devastating disease and that its estrogen drug, Premarin, could treat it. Soon, their public relations campaign created support for a National Osteoporosis Week and eventually, a National Osteoporosis Foundation (to which Wyeth contributed).
- 77. Wyeth also sought to claim that hormone therapy drugs, such as Premarin, could prevent or reduce cardiovascular disease. Indeed, Wyeth's sales representatives encouraged doctors to prescribe hormone therapy even if a woman was not having menopausal symptoms because of the therapy's purported cardiac benefits.
- 78. Wyeth claimed that the cardiac benefits of hormone therapy were proven by the Nurses Health Study. The Nurses Health Study was based on questionnaires of almost 122,000 female nurses, including 32,300 post-menopausal women. This study's results were published in

1985 and were clearly impacted by observational and selection bias since the population of nurses were health conscious and generally following better exercise and diet regiments than a general population. Moreover, the participants in The Nurses' Study were educated and compliant "patients"—actually nurses—who were more keenly aware of their health conditions and at a lower risk for heart disease regardless of hormone therapy. However, Wyeth ignored this obvious flaw and instead exaggerated the results to support its promotion of Premarin.

- 79. As a result of Wyeth's marketing efforts, between 1990 and 1995 Premarin became the most frequently dispensed prescription drug in the United States.
- 80. In approximately 1993, Wyeth distributed a videotape to consumers entitled, "What every woman should know about Estrogen." This videotape claimed to be a "seminar for women" and depicted a female doctor advising women about menopause and hormone therapy. Wyeth's video "seminar" warned of a wide variety of illnesses and ailments purportedly associated with menopause. Among other things, Wyeth represented that estrogen loss causes bones to become "brittle," skin to become "dryer," and sexual intercourse to become "painful and irritating." While Wyeth's video was exhaustive in its warnings about menopause, it glossed over the dangers and risks associated with hormone therapy. In its "What every woman should know about Estrogen" video seminar, Wyeth also represented to women that estrogen provided "long term health protection" and should be continued indefinitely, even after short term menopausal symptoms, such as hot flashes, had subsided. When a purported consumer inquired how long Premarin should be taken, Wyeth's doctor-spokesperson responded "anywhere from five to ten years in order to get protection from long term problems." And, with regard to breast cancer risks, Wyeth represented to women, through its video "seminar" that the benefits of taking estrogen "far outweigh[ed]" the risks for women unless they faced a particularly high risk

of breast cancer.

- 81. In 1994, Wyeth got approval for its next marketing blockbuster: combination hormone therapy in a single pill. Prempro is an oral medication that combines the estrogenic compound CEE with the progestin MPA in a single pill taken one time per day. A similar Wyeth product containing the same combination of compounds is brand named Premphase. Premphase delivers both CEE and MPA for only part of the monthly regime and then CEE alone without the MPA component for the rest of the month. Wyeth now had multiple hormone therapies in the "Premarin family of products" to market and promote.
- 82. Soon after introduction of Prempro, Wyeth agreed to fund a four year heart disease prevention trial, called HERS: Heart and Estrogen/Progestin Replacement Study. Wyeth touted the study as one that would show that that Prempro (its specific combination of CEE and MPA hormone therapy) prevented heart disease in women who were at high risk for heart disease. Wyeth was seeking FDA approval of the use of Prempro to prevent or reduce the risk of heart disease. But in 1998, the HERS investigators reported that hormone therapy did not reduce the rate of coronary heart disease events in women with heart disease and in fact dramatically increased the risk of heart disease and heart attack in those women, especially in the first year. The HERS results were immediately minimized or ignored by Wyeth and its sales representatives.
- 83. With no actual science to support its assertions, Wyeth continued an aggressive marketing plan with promotion directly to the patients. Beginning in early 1999, Wyeth even distributed a brochure to women through the waiting rooms of physicians' offices, that claimed, "Menopause isn't gone in a flash — its debilitating consequences can affect the rest of your life." The promotional brochure also directed women to "Take a few minutes to think about the

rest of your life" and listed a number of conditions which neither Prempro nor Premarin had been approved by the FDA to treat, including Alzheimer's disease, vision problems, tooth loss, heart disease, and colon cancer.

- In a magazine advertisement that featured model Lauren Hutton, Wyeth made a 84. rash of similar claims, suggesting that its hormone therapy drugs were appropriate for treating or preventing, among other things, memory loss, colon cancer, and age-related vision loss. In the March 19, 2000, edition of Parade Magazine, Wyeth spokesperson Lauren Hutton (who was not identified as a Wyeth spokesperson) was asked what she did to look good and feel fit and she answered: "[M]y number 1 secret is estrogen. It's good for your moods, it's good for your skin. If I had to choose between all my creams and makeup for feeling and looking good, I'd take the estrogen."
- A cornerstone of the marketing Wyeth program was promotion of hormone therapy for long-term use of indefinite duration. Specifically, JAMA reported that:

In 2000, 46 million prescriptions were written for Premarin (conjugated estrogens), making it the second most frequently prescribed medication in the United States and accounting for more that \$1 billion in sales, and 22.3 million prescriptions were written for Prempro (conjugated estrogens plus medroxyprogestrone acetate). While US Food and Drug Administration-approved indications for hormone therapy include relief of menopausal symptoms and prevention of osteoporosis, long-term use has been in vogue to prevent a range of chronic conditions, especially heart disease. [Emphasis added.]

86. Wyeth continued to press the FDA to approve the use of Prempro to prevent or reduce the progression of heart disease in post-menopausal women. The FDA did not believe there was sufficient scientific evidence to support such an indication/usage of the drug and denied Wyeth's request without reliable science from a controlled study to support the assertions. Even though the FDA had specifically not approved the use of Prempro for the prevention or

improvement of heart disease. Wyeth continued to promote Prempro as having this benefit and even represented to physicians that Prempro reduced cardiovascular mortality by 50%.

- 87. In the early 1990s, the Women's Health Initiative Study (WHI) was thus born. Conducted by the National Institutes of Health (NIH) and supported by Wyeth, this large scale, controlled study was designed to definitively allay any question about Prempro's heart, osteoporosis and mental cognition benefits.
- While Wyeth waited for the WHI study researchers to collect their data and reach 88. their conclusions, the drug maker's overzealous hormone therapy marketing effort continued. At least until mid-2002. Wyeth distributed a hormone therapy promotional brochure targeted for women consumers. The front cover stated: "Starting your Hormone Replacement Therapy (HRT)" and encouraged a woman to "Say yes to PREMPRO." The brochure contained testimonial statements from women taking Premoro, such as, "I wanted an HRT that was established, time tested, and had a successful track record. I'm delighted with PREMPRO" and "With PREMPRO, I know I've taken action to protect my health — and that's truly empowering." The unbalanced nature of Wyeth's marketing efforts is typified by the inadequate warnings contained in the "Side Effects" section of Wyeth's "Say yes to PREMPRO" brochure. In the warnings section. Wyeth only relate the risk of uterine cancer (associated with estrogenonly therapy), worsening diabetes, nausea, abdominal pain, irregular bleeding, headache, hair loss, and breast tenderness.
- On July 9, 2002, the National Heart, Lung and Blood Institute ("NHLBI"), a 89. federal agency and part of the National Institutes of Health ("NIH"), halted the WHI study because the investigators concluded that, under the circumstances, the risks of taking Prempro outweighed its benefits. The scientific papers discussing the results of the WHI study provided

the most comprehensive published data evaluating the risk and benefits of this drug combination of CEE and MPA. In July of 2002, the published results of the WHI provided the scientific and medical communities with important (although preliminary) information as to the varied and overwhelming risks associated with hormone therapy. Since July of 2002 there have been a number of additional findings and studies published and other studies evaluating these risks are ongoing currently.

- The results of the WHI study and other studies like it, contradict the scientific and 90. medical assertions that all Manufacturing Defendants had made for decades about their respective products. Manufacturing Defendants told the community of medical physicians who consistently prescribed these medications that the risks of these drugs were minimal and that there were great benefits ranging from symptom relief to the prevention of life threatening medical conditions like heart disease and osteoporosis.
- The Women's Health Initiative (WHI) was a study that focused on defining the 91. risks and benefits of strategies that could potentially reduce the incidence of heart disease, breast and colorectal cancer, and fractures in post-menopausal women. Between 1993 and 1998, the WHI enrolled 161,809 post-menopausal women volunteers in the age range of 50 to 79 years. The study was conducted at 40 clinical centers in the United States and was scheduled to last for 15 years. Participants in the combination therapy arm of the WHI study received Prempro because it contained both the progestin MPA as well as the estrogenic compound Premarin. The Prempro arm of the WHI involved 16,608 women ages 50 to 79 years with an intact uterus. An important objective of the trial was to examine the effect of this combination pill on the prevention of heart disease and hip fractures, and any associated change in risk for breast and colon cancer.

- 92. In 2000 and again in 2001, WHI investigators complied with a recommendation from the study's Data and Safety Monitoring Board (DSMB) to inform participants of a small increase in heart attacks, strokes, and blood clots in women taking hormones. The DSMB, an independent advisory committee charged with reviewing results and ensuring participant safety, found that the actual number of women having any one of these events was small and did not cross the statistical boundary established to ensure participant safety. Therefore, the group recommended continuing the trial due to the still uncertain balance of risks and benefits.
- 93. At the DSMB's meeting on May 31, 2002, the data review confirmed that the number of cases of invasive breast cancer in the estrogen plus progestin group had crossed the boundary established as a signal of increased risk. The DSMB's May 31, 2002, recommendation to stop the trial was based on the finding of increased breast cancer risk, supported by the evidence of overall health risks exceeding any benefits. On July 8, 2002 participants started receiving letters informing them about the results and telling them that they should stop study medications.
- 94. The WHI Study found that for the Prempro arm, when compared to placebo, there was an overall increased risk of the following adverse events:
  - (i) 41 % increase in strokes,
  - (ii) 29 % increase in heart attacks,
  - (iii) 100 % increase in venous thromboembolism (blood clots),
    - (iv) 22 % increase in total cardiovascular disease,
    - (v) 26 % increase in breast cancer.
- 95. The WHI Study concluded that the "Overall health risks exceeded benefits from use of combined estrogen plus progestin for an average 5.2-year follow-up among healthy post-

menopausal US women." The Study also found that the combination hormone regimen should not be initiated or continued for primary prevention of coronary heart disease.

96. Because of the importance of the report from the WHI investigators on the estrogen plus progestin study, the study was released early to the public on July 9, 2002, as an expedited article on the IAMA Web site. In commenting on the studies findings, NHLBI Director, Dr. Claude Lenfant, was unequivocal in his own conclusions:

> The cardiovascular and cancer risks of estrogen plus progestin outweigh any benefits—and a 26 percent increase in breast cancer risk is too high a price to pay, even if there were a heart benefit. Similarly, the risks outweigh the benefits of fewer hip fractures.

97. Dr. Jacques Roussow, acting director of the WHI and lead author of the JAMA article, summarized the risks of combination hormone therapy in very straightforward manner as he explained the statistical significance of the study results:

> The WHI results tell us that during 1 year, among 10,000 post-menopausal women with a uterus who are taking estrogen plus progestin, 8 more will have invasive breast cancer, 7 more will have a heart attack, 8 more will have a stroke, and 18 more will have blood clots, including 8 with blood clots in the lungs, than will a similar group of 10,000 women not taking these hormones. This is a relatively small annual increase in risk for an individual woman. Individual women who have participated in the trial and women in the population who have been on estrogen and progestin should not be unduly alarmed. However, even small individual risks over time, and on a population-wide basis, add up to tens of thousands of these serious adverse health events. Emphasis added.

- 98. It is now clear that hormone therapy poses substantial health risk with little or no corresponding benefit. These risks include breast cancer, ovarian cancer, heart attacks, strokes, deep vein thromboembolisms, pulmonary embolisms, gallbladder cancer and auto-immune diseases (such as lupus and scleroderma).
  - 99. Breast cancer risks - The connection between hormone therapy usage and breast

cancer found in the WHI studies were confirmed by a similar study conducted in the United Kingdom. The August 9, 2003, issue of Lancet, reported on the conclusions reached by The Million Women Study — a major research effort funded by Cancer Research UK — confirming that current and recent hormone therapy increases a woman's chance of developing breast cancer and that the risk goes up with duration of use. Scientists at the Cancer Research UK analyzed data from over one million women between the ages of 50 and 64. Researchers found that postmenopausal women using combination hormone therapy were twice as likely to develop breast cancer as non-users (a 100 per cent increase). Using the Million Women Study data, it is estimated that hormone therapy has caused more than 100,000 additional and unnecessary breast cancers in the United States of America alone.

- article published in JAMA. This article confirmed that the WHI data found that in addition to stimulating the growth of breast cancer, combination hormone therapy makes breast tumors harder to detect, leading to dangerous delays in diagnosis. The article reported that breast abnormalities could develop soon after a woman starts taking hormone therapy. Consequently, the study's findings raise questions about the safety of even short-term hormone use. In the same June 25, 2003, issue that reported this study, JAMA also published an editorial by Dr. Peter H. Gann, a cancer epidemiologist at Northwestern University, who stated that this study represents "further compelling evidence against the use of combination estrogen plus progestin hormone therapy."
- 101. Manufacturing defendants never adequately or appropriately warned physicians or users that estrogen therapy could cause or contribute to this risk.
  - 102. General cancer risk In addition to the studies published in JAMA, NEJM, and

other medical journals, a recent federal agency report also revealed that estrogen could be dangerous to women taking it as hormone therapy. On December 11, 2002, the National Institute of Environmental Health Sciences released its tenth annual report on carcinogens, which confirmed that estrogen is a "known human carcinogen."

- 103. It is now also clear that hormone therapy provides little real benefit beyond symptom alleviation. For even its approved indications, there were safer alternative medications that provided better results with less risk. Indeed, rather than providing any heart benefit or mental cognition benefit, hormone therapy actually dramatically increases the risk of heart attack and stroke, especially in the first year of use, and reduces a woman's mental functioning. Hormone therapy has now also been associated with hearing loss and osteoarthritis.
- Cardiac benefits In the August 7, 2003, issue of NEJM, the WHI study continued to yield important information regarding the safety of hormone therapy use. The study found that combination hormone therapy does not protect the heart and may even increase the risk of coronary heart disease (CHD). Specifically, the WHI study found that combination hormone therapy usage was associated with a 24% overall increase in the risk of CHD (6 more heart attacks annually per 10,000 women using combination therapy) and a 81% increased risk of CHD in the first year after starting combination therapy.
- 105. Osteoporosis benefits - Manufacturing Defendants were aware (or should have known) that other therapies for osteoporosis, including Fosamax, provided better osteoporosis prevention and treatment benefits with less risk. On May 21, 2003, JAMA published another study studying the efficacy of estrogen plus progestin therapy (e.g., Prempro) for prevention of bone loss in elderly women. The study involved 373 women ages 65 to 90 who had either thinning bones or full-blown osteoporosis and took one of four treatments for three years: (I)

combination hormone therapy alone, (ii) a bone-building drug, alendronate (which is sold under the brand name, Fosamax), (iii) combination hormone therapy with Fosamax, or (iv) a placebo. This study found that Fosamax alone was more effective than combination hormone therapy alone in combating osteoporosis. After three years, hipbone density had increased nearly 6 percent in women on hormone therapy with Fosamax; 4 percent in those on Fosamax alone, and 3 percent in the hormones-only group. Yet, manufacturing defendants continued to overpromote and exaggerate the hormone drugs' purported benefits.

- another study on the effects of hormone therapy, this time focusing on the risk of Alzheimer's disease and other types of dementia. The study found that combination hormone therapy Prempro doubled the risk of dementia for woman who started hormones at age 65 or older. The Dementia study was based on a four-year trial involving 4,532 women at 39 medical centers, where half of the volunteers took placebo pills and half took Prempro. In four years, there were 40 cases of dementia in the Prempro group and 21 in the placebo group. Translated to an annual rate for the population-at-large, the results mean that for every 10,000 women 65 and older taking hormone therapy, there will be 45 cases of dementia a year with 23 of them attributable to hormone use. Dr. Sally A. Shumaker, the director of the dementia study and a professor of public health sciences at Wake Forest University, stated that study's "clear message is that there's no reason for older women to be taking combination hormone therapy."
- 107. Quality of Life benefits On March 17, 2003, the New England Journal of Medicine (NEIM) released a follow-up WHI study which reported that hormone therapy failed to improve the quality of life for menopausal women. The Quality of Life study examined the same pool of 16,000 WHI women and found that hormone therapy drugs do not provide the very

benefit that encourages women to take the treatment — that is, to make them feel happier and healthier after menopause. A comparison of women who took hormone therapy to women given a placebo showed those women taking hormones did not report sleeping better or feeling better. The hormone therapy group also did not report less depression or more sexual satisfaction than the placebo group.

- 108. According to the study's lead author, Dr. Jennifer Hays: "Its just not something that's going to make most women feel better. Even if it reduces your symptoms, that's not going to translate into a meaningful effect on a quality of life."
- 109. For years, Manufacturing Defendants have promoted hormone therapy as drugs of prevention as well as being safe and effective. The reality is the exact opposite.
- 110. In the face of the now published independent studies, it is clear that the warnings and labels provided by Manufacturing Defendants were inadequate, misleading, and inaccurate. Manufacturing Defendants minimized the risks of these drugs to the prescribing physicians and ultimate users while simultaneously exaggerating the purported benefits. Physicians and patients had no ability to conduct a realistic risk versus benefit assessment.
- 111. Manufacturing Defendants provided inadequate warnings concerning hormone therapy as to breast cancer. Indeed, while the Prempro warning mentioned the risk of breast cancer with conjugated estrogens (the Premarin component of Prempro), it also emphasized that, with regard to the effect of added progestins on the risk of breast cancer: "The overall incidence of breast cancer does not exceed that expected in the general population." The WHI study plainly reveals that this warning is false and was known or should have been known by Wyeth and all other Manufacturing Defendants for decades.
  - 112. Manufacturing Defendants provided inadequate warnings concerning hormone

therapy as to cardiac damage. For example, under Precautions, the Prempro label acknowledges: "The effects of estrogen replacement therapy on the risk of cardiovascular disease have not been adequately studied." Nevertheless, Wyeth had long promoted the benefits of long term hormone therapy for cardiovascular disease.

113. Manufacturing Defendants represented that hormone therapy was safe for long-term use. It was not until January 6, 2003 that Wyeth abandoned this long-standing marketing strategy and cautioned physicians in a "Dear Doctor" letter that "estrogens and estrogens plus progestin should be prescribed for the shortest duration consistent with treatment goals. In early June 2003, Wyeth brought their new marketing campaign to the public with a new public relations campaign consisting of full-page advertisements placed in 180 newspapers nationwide. The advertisement, styled as "A Message from Wyeth," revealed Wyeth abandonment of its long-term strategy of promoting long-term usage of Premarin and Prempro for post-menopausal women for a variety of conditions, stating in part, that:

Hormone therapy is not a lifelong commitment.... As a result of recent studies, we know that hormone therapy should not be used to prevent heart disease. These studies also report an increased risk of heart attack, stroke, breast cancer, blood clots, and dementia. Therefore, it is recommended that hormone therapy (estrogen, either alone or with progestin) should be taken for the shortest duration at the lowest effective dose.

114. Manufacturing Defendants represented that hormone therapy was safe at the dosages recommended over the years even though Defendants knew for years that lower doses of these medications was just as effective and with less risk. It was again not until 2003, that Manufacturing Defendants including Wyeth cautioned physicians to use the lowest possible dose. Indeed, Wyeth created an entire new marketing strategy called "Go low with Prempro" and launched a new, lower dose combination treatment.

- 115. Manufacturing Defendants represented that hormone therapy had benefits that were not supported by reliable science and failed to conduct the necessary pre-approval research and post-approval surveillance to establish the safety of long-term hormone therapy regimen. It was left to independent studies to uncover the serious risks that Manufacturing Defendants knew about (or in the exercise of reasonable care could have known about) these drugs. Manufacturing Defendants never to physicians and patients that no long-term testing had not been performed on these drugs, thereby fraudulently inducing physicians and patients alike to use these products with the false assumption that such drugs had been sufficiently tested.
- The manufacturers of generic equivalent MPA as well as brand-name Provera 116. were aware that MPA would be prescribed as a part of combination hormone therapy. Indeed, Manufacturing Defendants marketed, promoted and sold their MPA for such combination use. Manufacturing Defendants knew, or in the exercise of reasonable care should have known, that the synthetic progestin was harmful, defective in design, would exaggerate or accelerate the harmful effects of estrogen and the combination therapy of estrogen with MPA would be unreasonably dangerous for use. In fact, MPA, when used in combination hormone therapy has deleterious effects, including increasing the incidence of strokes, blood clots, heart attacks, breast cancers, and ovarian cancer. Even though Manufacturing Defendants knew of these risks, they did not warn consumers of the serious adverse side effects of this form of combination hormone therapy in any of their respective labels or promotional materials.
- 117. Further Manufacturing Defendants in their manufacture of generic equivalent and brand-name MPA failed to conduct adequate pre-marketing clinical testing and research to determine the safety of MPA when used in combination with estrogenic compounds like Premarin. Manufacturing Defendants also failed to conduct adequate post-marketing

surveillance to determine the safety of MPA when used in combination with estrogenic compounds. Nevertheless, Manufacturing Defendants never disclosed on their respective warning labels that such testing had not been performed, thereby fraudulently inducing physicians and patients alike to use the MPA drugs with the false assumption that such drugs had been sufficiently tested.

### FIRST CAUSE OF ACTION STRICT PRODUCTS LIABILITY-FAILURE TO WARN

- 118. Plaintiff incorporates by reference each and every paragraph of the General Allegations as though set forth in full in this cause of action.
- 119. The drug product previously described was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution, in that, and not by way of limitation, said product and its warnings, instructions and directions failed to warn of the dangerous propensities of said product, which risks were known or reasonably scientifically knowable to defendants. Defendants and each of them, knew or should have known of the defective condition, characteristics and risks associated with said product, as previously set forth herein.
- 120. At all times herein mentioned, the aforementioned product was defective, and defendants, and each of them, knew that the product was to be used by the user without inspection for defects therein. Moreover, plaintiff neither knew, nor had reason to know at the time of the use of the subject products, of the existence of the aforementioned defects.
- 121. As a result of the defective condition of the aforementioned product, plaintiff suffered injuries and damages as alleged herein.
  - 122. By reason of the facts and premises aforesaid, plaintiff sustained damages in a

sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

#### SECOND CAUSE OF ACTION NEGLIGENCE

- Plaintiff incorporates by reference each and every paragraph of the General Allegations as though set forth in full in this cause of action.
- At all times herein mentioned, defendants, and each of them, had a duty to properly manufacture, design, formulate, compound, test, product, process, assemble, inspect, research, distribute, market, label, package, prepare for use, sell, prescribe and adequately warn of the risks and dangers of the aforementioned product.
- At all times herein mentioned, defendants, and each of them, negligently and 125. carelessly tested, studied, researched, evaluated, endorsed, manufactured, designed, formulated, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold the aforementioned products and failed to adequately test and warn of the risks and dangers of the aforementioned product.
- As a result of said negligence and carelessness of defendants, and each of them, 126. plaintiff suffered injuries and damages as alleged herein.
- By reason of the facts and premises aforesaid, plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

### THIRD CAUSE OF ACTION BREACH OF IMPLIED WARRANTY

- 128. Plaintiff incorporates by reference herein each and every paragraph of the General Allegations as though set forth in full in this cause of action.
- 129. Prior to the time that the aforementioned products were used by plaintiff, defendants, and each of them, impliedly warranted to plaintiff and plaintiff's agents and physicians that said product was reasonably fit and safe for its intended purposes, and was of marketable quality throughout.
- 130. Plaintiff was and is unskilled in the research, design and manufacture of the aforementioned product and reasonably relied entirely on the skill, judgment and implied warranty of the defendants in using the aforementioned product.
- 131. The aforementioned product was neither safe for its intended use nor of merchantable quality, as warranted by defendants, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.
- 132. As a result of the aforementioned breach of implied warranties by defendants and each of them, plaintiff suffered injuries and damages as alleged herein.
- 133. By reason of the facts and premises aforesaid, plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

## FOURTH CAUSE OF ACTION BREACH OF EXPRESS WARRANTY

134. Plaintiff incorporates by reference herein each and every paragraph of the General Allegations as though set forth in full in this cause of action.

- At the time and place of the sale, distribution and supply of said products, defendants, and each of them, expressly represented and warranted that hormone replacement therapy was safe and well accepted by patients studied. Defendants, and each of them, expressly warranted to physicians and their health-care patients that said drug was a prescription drug fit for the use for which it was intended and was of merchantable quality, despite the fact that the product was unfit and unsafe for ingestion by healthcare patients in light of a known propensity to cause serious side effects, including but not limited to severe and even fatal injuries to persons ingesting said product. In reliance upon said warranties, said product was prescribed to plaintiff and purchased by plaintiff.
- 136. In utilizing the aforementioned product, plaintiff relied on the skill, judgment, representations and foregoing express warranties of defendants, and each of them. Said warranties and representations were false in that the aforementioned product was not safe and was unfit for the uses for which it was intended.
- As a result of the foregoing breach of express warranties by defendants, and each 137. of them, plaintiff sustained the injuries and damages as herein alleged.
- By reason of the facts and premises aforesaid, plaintiff sustained damages in a 138. sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

#### IFTH CAUSE OF ACTION CEIT BY CONCEALMENT

Plaintiff incorporates by reference herein each and every paragraph of the General Allegations as though set forth in full in this cause of action.

- Defendants, and each of them, from the time that the aforementioned product was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, willfully deceived plaintiff by concealing from plaintiff, plaintiff's physicians and the general public, the true facts concerning said pharmaceutical product, which defendants had a duty to disclose.
- At all times herein mentioned, defendants, and each of them, conducted a sales and marketing campaign to promote the sale of the aforementioned drug product and willfully deceive plaintiff, plaintiff's physicians and the general public as to the health risks and consequences of the use of the aforementioned products. Defendants, and each of them, were aware of the foregoing, and that the aforementioned product was not same, fit and effective for human consumption, the use of said product is hazardous to health, and said product has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by plaintiff as delineated herein.
- Defendants intentionally concealed and suppressed the true facts concerning said pharmaceutical product with the intent to defraud plaintiff, in that defendants knew that plaintiff's physicians would not prescribe the subject products, and plaintiff would not have used the subject product, if they were aware of the true facts concerning the dangers of said product.
- As a result of the foregoing fraudulent and deceitful conduct by defendants, and each of them, plaintiff suffered injuries and damages as alleged herein.
- By reason of the facts and premises aforesaid, plaintiff sustained damages in a 144. sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

- 145. Plaintiff incorporates by reference herein each and every paragraph of the General Allegations as though set forth in full in this cause of action.
- 146. Defendants, and each of them, from the time that the aforementioned product was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, made false misrepresentations, as previously set forth herein, to plaintiff, plaintiff's physicians and the general public, including but not limited to the misrepresentation that said pharmaceutical product, was safe, fit and effective for human consumption. At all times herein mentioned, defendants, and each of them, conducted a sales and marketing campaign to promote the sale of the aforementioned drug product and willfully deceive plaintiff, plaintiff's physicians and the general public as to the health risks and consequences of the use of the aforementioned product.
- 147. Defendants made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by defendants, by sales representatives and other authorized agents of said defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.
- 148. The foregoing representations by defendants, and each of them, were in fact false, in that the aforementioned product was not same, fit and effective for human consumption, the use of said product is hazardous to health, and said product has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by plaintiff as delineated herein.
  - 149. The foregoing representations by defendants, and each of them, were made with

the intention of inducing reliance and the prescription, purchase and use of the subject product.

- In reliance on the misrepresentations by defendants, and each of them, plaintiff 150. was induced to purchase and use the use of the aforementioned product. If plaintiff had known of the true facts and the facts concealed by defendants, plaintiff would not have used the subject product. The reliance of plaintiff upon defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.
- As a result of the foregoing negligent misrepresentations by defendants, and each 151. of them, plaintiff suffered injuries and damage as alleged herein.
- By reason of the facts and premises aforesaid, plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter,

#### SEVENTH CAUSE OF ACTION. STRICT PRODUCT LIABILITY- DESIGN DEFECT

- Plaintiff incorporates by reference herein each and every paragraph of the General 153. Allegations as though set forth in full in this cause of action.
- Defendants and each of them are the manufacturers, distributors, sellers, and/or suppliers of combination hormone replacement therapy administered to Plaintiff.
- The combination hormone replacement therapy medications manufactured and/or 155. supplied by defendants were defective in design or formulation in that, when it left the hands of defendants, the foreseeable risks of harm grossly exceeded the benefits associated with the design or formulation of the drugs.

- . ...
- 156. The hormone replacement therapy medications were expected to and did reach plaintiff without substantial change in their condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned and otherwise distributed.
- 157. Plaintiff used hormone replacement therapy in a manner for which it was intended or in a reasonably foreseeable manner.
- 158. Defendants' hormone replacement therapy caused increased risks of personal injury and harm upon consumption, and therefore constitute a product unreasonably dangerous for normal use due to their defective design, defective manufacture, and defendants' misrepresentations and inadequate facts disclosed to plaintiff.
- 159. The hormone replacement therapy medications manufactured and/or supplied by defendants were defective due to:
- (a) Defective design or formulation in that when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation;
- (b) Defective marketing in that defendants made inappropriate, misleading, inaccurate and incomplete representations about this product in advertisements, news, commercials, and direct to consumer advertisements. These deceptive marketing representations were made to the FDA, healthcare providers, pharmacists and the public. These deceptive marketing representations were made in order to induce sales and increase profits;
- (c) Defective design or formulation, in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect, and more dangerous than other hormone replacement therapy

medications;

- (d) Inadequate warnings or instructions because defendants knew or should have known that the product created a risk of dangerous side effects and other related conditions and diseases:
- (e) Inadequate pre-marketing testing which, if conducted properly, would have revealed the serious problems with this drug prior to the first sale; and/or
- (f) Inadequate post-marketing warning or instruction because, after defendants knew or should have known of the risk of dangerous side effects and other related conditions and diseases, they failed to provide adequate warnings to users or consumers of the product and continued to promote the product.
  - 160. Defendants, therefore, are strictly liable to plaintiff.
- 161. As the proximate cause and legal result of the defective condition of the hormone replacement therapy as manufactured and/or supplied by defendants, and as a direct and legal result of the negligence, carelessness, and other wrongdoing and actions of defendants:
- (a) Plaintiff has been seriously injured in health, strength, and activity and has suffered injuries to her body and mind, specifically brain injuries, the exact nature and extent of which are not known at this time, plaintiff has also sustained economic loss, including loss of earnings and diminution or loss of earning capacity, of which the exact amount is presently unknown;
- (b) Plaintiff has required reasonable, necessary, and constant health care, attention, and services and has thereby incurred extreme medical, health, incidental and related expenses.

  Upon information and belief, plaintiff further alleges that she will require medical and/or hospital care, attention and services in the future in an amount as yet unascertained.

- 162. Defendants' actions, described above were performed willfully, intentionally, with malice and / or with reckless disregard for the rights of plaintiff and the public. As such, plaintiff is entitled to punitive damages against defendants.
- By reason of the facts and premises aforesaid, plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

WHEREFORE, plaintiff prays for judgment against defendants, and each of them, as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of plaintiff:

- A sum which exceeds the jurisdictional limits of all lower courts which the jury / **(1)** would find to be fair, adequate and just, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;
- **(2)** A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;
- (3) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this matter,
- A sum which exceeds the jurisdictional limits of all lower courts which the jury (4) would find to be fair, adequate and just, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;
  - (5) A sum which exceeds the jurisdictional limits of all lower courts which the jury

would find to be fair, adequate and just, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

- (6) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action; and
- (7) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action; together with the interest, costs and disbursements of this Action.

Yours, etc.,

FINKELSTEIN & PARTNERS, LLP Attorneys for Plaintiff Office & P.O. Address 436 Robinson Avenue Newburgh, New York 12550

BV-

ANDREW G. FINKELSTEIN, ESQ.

WYETH
5 Giralda Farms
Madison, New Jersey 07940

WYETH PHARMACEUTICALS INC. c/o WYETH 5 Giralda Farms Madison, New Jersey 07940

WYETH-AYERST PHARMACEUTICALS, INC. c/o WYETH
5 Giralda Farms
Madison, New Jersey 07940

WYETH PHARMACEUTICALS, c/o WYETH 5 Giralda Farms Madison, New Jersey 07940

PFIZER INC. 235 East 42<sup>nd</sup> Street New York, NY 10017

PHARMACIA & UPJOHN, INC. c/o PFIZER INC. 235 East 42<sup>nd</sup> Street New York, NY 10017

PHARMACIA & UPJOHN COMPANY c/o PFIZER INC. 235 East 42<sup>nd</sup> Street New York, NY 10017

PHARMACIA & UPJOHN LLC. c/o PFIZER INC. / 235 East 42<sup>nd</sup> Street New York, NY 10017

PHARMACIA & UPIOHN COMPANY LLC. c/o PFIZER INC. 235 Bast 42<sup>nd</sup> Street New York, NY 10017

PHARMACIA CORPORATION, c/o PFIZER INC. 235 East 42<sup>nd</sup> Street New York, NY 10017

#### STATE OF NEW YORK, COUNTY OF ORANGE ss:

I, the undersigned, am an attorney admitted to practice in the courts of New York State, and say that:

I am the attorney of record, or of counsel with the attorney(s) of record, for the plaintiff. I have read the annexed Verified Complaint know the contents thereof and the same are true to my knowledge, except those matters therein which are stated to be alleged on information and belief, and as to those matters I believe them to be true.

My belief, as to those matters therein not stated upon knowledge, is based upon the following:

Facts and information contained in deponent's file. The reason I make this affirmation instead of the plaintiff is because the plaintiff resides outside of the county where deponent maintains his office.

I affirm that the foregoing statements are true under penalties of perjury.

Dated: October 9, 2007

ANDREW G. FINKELSTEIN, ESQ.

## **EXHIBIT B**

| UNITED STATES DISTRICT COURT        |             |   |                    |
|-------------------------------------|-------------|---|--------------------|
| SOUTHERN DISTRICT OF NEW YORK       |             | v |                    |
|                                     |             | : |                    |
| SUSAN MARSA,                        |             | : |                    |
| •                                   | Plaintiff,  | : | Civil Action No.   |
| - against -                         |             | ; |                    |
| WYETH, WYETH PHARMACEUTICAL         | S INC.,     | : |                    |
| WYETH-AYERST PHARMACEUTICAL         | S, INC.,    | : | 4                  |
| WYETH PHARMACEUTICALS, PFIZER INC., |             | : |                    |
| PHARMACIA & UPJOHN, INC.,           |             | : | CONSENT TO REMOVAL |
| PHARMACIA & UPJOHN COMPANY,         |             | : |                    |
| PHARMACIA & UPJOHN, LLC.,           | •           | : |                    |
| PHARMACIA & UPJOHN COMPANY L        | LC. and     | • |                    |
| PHARMACIA CORPORATION,              |             | : |                    |
|                                     | Defendants. | : |                    |
|                                     | <del></del> | X |                    |

Defendants Pfizer Inc., Pharmacia & Upjohn Company LLC (f/k/a "Pharmacia & Upjohn Company") (incorrectly also named herein as "Pharmacia & Upjohn Company,") Pharmacia & Upjohn LLC (f/k/a "Pharmacia & Upjohn Inc.") (incorrectly also named herein as "Pharmacia & Upjohn Inc.") and Pharmacia Corporation, without waiver of service and other defenses (including, but not limited to, failure to state a claim against any of these defendants), hereby consent to removal of the above-captioned action from the Supreme Court of the State of New York, New York County (Index No. 07/113891) to the United States District Court for the Southern District of New York.

Dated: New York, New York November 21, 2007

Respectfully submitted,

Alan E. Rothman, Esq. Kaye Scholer LLP 425 Park Avenue

New York, New York 10022

(212) 836-8000

Attorneys for Pfizer Inc., Pharmacia & Upjohn Company LLC (f/k/a "Pharmacia & Upjohn Company") (incorrectly also named herein as "Pharmacia & Upjohn Company,") Pharmacia & Upjohn LLC (f/k/a "Pharmacia & Upjohn Inc.") (incorrectly also named herein as "Pharmacia & Upjohn Inc.") and Pharmacia Corporation

# EXHIBIT C

#### DLA PIPER US LLP

1251 Avenue of the Americas
New York, New York 10020-1104
(212) 335-4500
Attorneys for Defendants
WYETH and WYETH PHARMACEUTICALS

SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK

SUSAN MARSA,

Index No. 07/113891

Plaintiff.

- against -

WYETH, WYETH PHARMACEUTICALS INC., WYETH-AYERST PHARMACEUTICALS, INC., WYETH PHARMACEUTICALS, PFIZER INC., PHARMACIA & UPJOHN, INC., PHARMACIA & UPJOHN COMPANY, PHARMACIA & UPJOHN, LLC., PHARMACIA & UPJOHN COMPANY LLC. and PHARMACIA CORPORATION,

Defendants.

NOTICE OF FILING OF NOTICE OF REMOVAL

PLEASE TAKE NOTICE that on November 26, 2007, Wyeth and Wyeth Pharmaceuticals Inc., Defendants in the captioned action, removed this action to the United States District Court, Southern District of New York, by filing a Notice of Removal in that Court. A copy of the Notice of Removal is annexed hereto. Accordingly, and pursuant to 28 U.S.C. § 1446(d), this Court may proceed no further unless and until the case is remanded.

Plaintiff also names Wyeth-Ayerst Pharmaceuticals Inc. (incorrectly named as Wyeth-Ayerst Pharmaceuticals, Inc.) and Wyeth Pharmaceuticals. Wyeth-Ayerst Pharmaceuticals Inc. changed its name to Wyeth Pharmaceuticals Inc. on March 22, 2002. Wyeth Pharmaceuticals is a division of Wyeth.

Dated: New York, New York November 21, 2007

DLA PIPERJUS LLI

By:

Heidi Levine, Esq.

Eric M. Falkenberry, Esq.

1251 Avenue of the Americas New York, New York 10020-1104 212-335-4500 Attorneys for Defendants

Wyeth and Wyeth Pharmaceuticals Inc.

TO: Andrew G. Finkelstein, Esq. Finkelstein & Partners, LLP 436 Robinson Avenue Newburgh, New York 12550

Attorneys for Plaintiff

Alan E. Rothman, Esq. Kaye Scholer LLP 425 Park Avenue New York, New York 10022-3598

Attorneys for Defendants Pfizer Inc.,
Pharmacia & Upjohn Company LLC (f/k/a
"Pharmacia & Upjohn Company")
(incorrectly also named herein as
"Pharmacia & Upjohn Company,")
Pharmacia & Upjohn LLC (f/k/a
"Pharmacia & Upjohn Inc.") (incorrectly
also named herein as "Pharmacia &
Upjohn Inc.") and Pharmacia Corporation